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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,316	12/11/2000	Yasuhiko Shimizu	55475(968)	7005

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EDWARDS & ANGELL, LLP
P.O. BOX 55874
BOSTON, MA 02205

EXAMINER

BOYD, JENNIFER A

ART UNIT PAPER NUMBER

1771

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/719,316

Applicant(s)

SHIMIZU, YASUHIKO

Examiner

Jennifer A Boyd

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5 and 7-10 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 5, 7- 8 and 10 is/are rejected.
7) ☒ Claim(s) 1-3 and 9 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION***Response to Amendment***

1. The Applicant's Amendments and Accompanying Remarks, filed April 16, 2004, have been entered and have been carefully considered. Claims 5 and 8 are amended, claims 1 – 3 and 9 are previously allowed and claims 1 – 3, 5 and 7 – 10 are pending. In view of Applicant's Amendments, the Examiner withdraws the 35 U.S.C. 112 rejection of claims 8 and 10 as detailed in paragraphs 2 – 3 of the previous Office Action dated October 15, 2003. In view of Applicant's Amendments, the Examiner withdraws the 35 U.S.C. 102(e) rejection of claims 5 and 7 as detailed in paragraph 5 of the previous Office Action dated October 15, 2003. Despite these advances, the invention as currently claimed is not found to be patentable for reasons herein below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

3. Claims 1, 5 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2 – 3, 7 and 9 – 10 are rejected for being dependent on rejected claims 1, 5 and 8.

4. The terms "fabric-like" and "plate-like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP

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§ 2173.05(d). How is the non-woven “fabric-like” and how are the fibers “plate-like”? It is suggested to the Applicant to amend the language replacing “fabric-like” with fabric and “plate-like” with “plate”.

Claim Rejections - 35 USC § 102/103

5. Claims 5 and 7 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bell (US 6,179,872).

Bell is directed to a biopolymer matt for use in tissue repair and reconstruction (Title).

As to claim 5, Bell teaches a nonwoven made of biopolymers such as collagen (column 12, lines 15 – 20). Bell teaches that objects can be embedded in the nonwoven material to alter its tear properties such as fragments of resorbable polymers (column 10, lines 15 – 30). Bell teaches that resorbable polymers include poly-L-lactic acid (polylactic acid) and poly-L-glycolic acid (polyglycolic acid) (column 12, lines 27 – 33).

As to claim 7, Bell teaches that the matt of collagen material or composite matt may be washed by various mild methods such as 0.001 – 0.1 M hydrochloric acid (column 16, lines 15 – 23). Bell teaches that the washing step occurs after freeze drying and can be freeze dried again after the washing step (column 16, 25 – 30).

Although Bell does not explicitly teach the claimed collagen material having one-point support tensile force of at least 5 N and rupture resistance tensile force of at least 15 N in the wet state (for a thickness of 1 mm), it is reasonable to presume that collagen material having one-point support tensile force of at least 5 N and rupture resistance tensile force of at least 15 N in the wet state (for a thickness of 1 mm) is inherent to Bell.

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Support for said presumption is found in the use of like materials (i.e. a collagen material comprising a non-woven fabric-like matrix composed of collagen and embedded with resorbable polymers such as polylactic acid or polyglycolic acid) which would result in the claimed property. The burden is upon the Applicant to prove otherwise. *In re Fitzgerald* 205 USPQ 594. In addition, the presently claimed property of collagen material having one-point support tensile force of at least 5 N and rupture resistance tensile force of at least 15 N in the wet state (for a thickness of 1 mm) would obviously have been present once the Bell product is provided. Note *In re Best*, 195 USPQ at 433, footnote 4 (CCPA 1977).

Claim Rejections - 35 USC § 103

6. Claims 8 and 10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bell (US 6,179,872) in view of Yasuhiko (WO 98/22157). The details of the rejection can be found in paragraph 7 of the previous Office Action dated October 15, 2003. The rejection is maintained.

Allowable Subject Matter

7. Claim 1 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office Action. The details of the allowance are detailed in paragraph 8 of the previous Office Action dated October 15, 2003.

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8. Claims 2 – 3 and 9 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

9. Applicant's arguments filed April 16, 2004 have been fully considered but they are not persuasive.

In response to Applicant's Arguments that Applicant's collagen material has superior strength compared to the prior art collagen material of Bell, the Examiner notes that all the claimed physical limitations has been met by Bell. Therefore, it is asserted that the claimed one-point support tensile force of at least 5N and rupture resistance tensile force of at least 15 N in the wet state is inherent to Bell. If said property is not inherent, it is asserted that Applicant's claim must be incomplete. In other words, if Applicant's asserts a lack of inherency in the prior art, then Applicant's claimed invention is missing an element that is critical to the invention, which would patentably distinguish it from the known prior art. The Examiner notes that the Applicant states in page 6 of the Remarks dated April 16, 2004 that a very high pressure of approximately 500 kgf/cm² is used in the production process. If this pressure creates the improved strength properties of the present invention, it is suggested that the Applicant include the limitation in the claims and change the structure of the claims to be product-by-process claims.

In response to Applicant's Arguments that Yasuhiko in combination with Bell

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does not teach Applicant's invention, the Examiner respectfully argues the contrary. It should be noted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The Examiner uses the Bell reference to set forth the embedding of a resorbable polymer into a collagen non-woven matt. The Examiner has incorporated Yasuhiko to set forth the exact structure of the collagen fibers within the matt and the tensile strength of the matt. In combination, the Examiner suggests that Yasuhiko can be used to modify the non-woven structure of the resorbable polymer embedded non-woven of Bell to create a material with good medical characteristics and the capability of suturing as suggested by Yasuhiko on page 5, paragraph 1.

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Conclusion

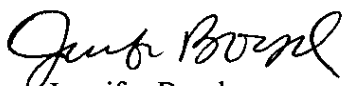
10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

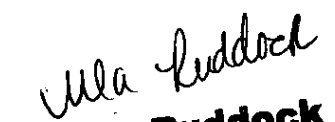
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A Boyd whose telephone number is 571-272-1473. The examiner can normally be reached on Monday thru Friday (8:30am - 6:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on 571-272-1478. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jennifer Boyd
June 15, 2004


Ula C. Ruddock
Primary Examiner
Tech Center 1700